Remarks

Claims 1 through 41 remain pending in the application.

The Office Action rejects claim 1 through 6, 11 through 16, 21 through 26 and 31 through 36 as obvious over Barry, Stent and Therapeutic Delivery System, U.S. Patent 5,439,446 (Aug. 8, 1995) in view of Stevens, et al., Method for delivery of Therapeutic Agents to the Heart, U.S. Patent 6,152,141 (Nov. 28, 2000), under the assertion that Barry discloses a stent and administration of therapeutic agents to reduce the risk of restenosis, that Barry discloses a catheter with a balloon and stent, and that the catheter has a port proximal to the balloon for injecting anti-restenosis agents in the "volume," but that Barry does not disclose use of his stent and therapeutic agent in the coronary blood vessel and in the myocardium, and the further assertion that Stevens discloses a method of delivery of therapeutic agents to the heart using a catheter with a delivery port to deliver a therapeutic agent to the myocardium. The Examiner argues that it would have been obvious to combine Barry with Stevens to place the Barry apparatus within the coronary blood vessel, and inject therapeutic agent into the myocardium. The Examiner further states that the stent can be placed in the endocardial or peri-adventitial area, which would mean that the therapeutic agent will be injected into the myocardium from those areas, and that the needle can be placed anywhere, such as at a site distal to the stent.

The Examiner's assertion that Barry's stent, or any stent, could be placed in the endocardial or peri-adventitial area of a coronary artery is not understood. If the Examiner is

suggesting that one of skill in the art would, in the treatment of stenosis or restenosis, place the stent in the endocardium or outside the blood vessel (peri-adventitial means "situated on the outside of the adventitia, or outer coat of a blood-vessel"), the Applicant requests further explanation and evidentiary support that this might be done to treat stenosis. Presently, Applicant knows of nothing in the art that would suggest that jamming a stent into the myocardium near a stenotic lesion would have any beneficial inhibitory effect on stenosis or restenosis, but does understand that such erroneous placement of the stent outside the intended artery is quite dangerous. Intentional dissection, the likely dislodgement of a stent shoved into the myocardium, and other iatrogenic trauma is counter to the goal of treating the stenotic lesion. On the other hand, the claimed method enables drug placement and delivery using previously poorly understood lymphatic fluid pathways, achieving the goal of drug delivery into the stenotic lesion while avoiding the iatrogenic damage inherent in Examiner's suggested approach.

The rejection of claims 1 through 6, 11 through 16, 21 through 26, and 31 through 36 is not supported with any suggestion that there is a motivation to make the Examiner's proposed combination. Though many drug delivery catheters could be used to accomplish the claimed methods, the Examiner confuses the possibility of doing so with a motivation to do so. The mere fact that a claimed combination could have been made says nothing regarding the required analysis for determining if the claimed method is patentable. The rejection is not supported by such an analysis, as it does not identify any motivation in the art to combine the references as suggested by the Examiner.

Accordingly, the Examiner has not made out a prima facie case of obviousness and the claims should be allowed.

The Office Action rejects claims 7 through 9, 17 through 19, 27 through 29 and 37 through 39 as obvious over Barry and Stevens in view of Mixson, Carrier: DNA complexes containing DNA encoding anti-angiogenic peptides and their use in gene therapy, U.S. Patent 6,080,728 (Jun. 27, 2000) under the assertion that Mixson discloses carrier vehicles for anti-angiogenic agents comprising micelles and micro spheres. Mixson, however, does not provide any suggestion to use his compounds for controlling stenosis, or doing so in combination with stent placement. Mixson teaches use of anti-angiogenic proteins to kill tumors. Even considered with the other references, Mixson does not suggest use in the claimed method. This rejection, like the rejection of the parent claims, is not supported by any purported motivation to make the combination. The examiner does not suggests how artisans would suspect that, if injected into the myocardium downstream in the coronary vasculature relative to a stenotic lesion, Mixson's compounds would have any beneficial effect on the stenotic lesion. The more likely expectation, from the knowledge that Mixson's compounds were useful to suppress tumors, would be some deleterious effect on the function of the heart wall. In light of the deleterious effect that Mixson's compounds have on tumors into which they are injected, Applicant suggests that it would require an explicit suggestion in the art to accomplish the claimed method. In any event, the utter lack of a motivation to make the combination indicates that a prima facie case of obviousness has not been made out, and the claims should be allowed.

The Office Action rejects claims 10, 20, 30 and 40 as obvious over Stevens in view of Rossi, et al., Chimeric DNA/RNA Ribozymes Containing Propanediol, U.S. Patent 6,379,931 April 30, 2002) under the assertion that Rossie discloses that therapeutic agents encapsulated in liposomes can be injected to inhibit stent-induced restenosis. The Examiner cites Rossi, col. 6, ll. 63-67, which states "Liposomes containing a ribozyme designed to inhibit stent-induced re-stenosis can be administered by balloon catheterization." The cited passage certainly does not suggest injection of liposomes into the myocardium. "Administration by balloon catheterization" might mean that the liposomes are coated on the balloon, but that is clearly not an injection.

Claim 41 is rejected as obvious over Stevens in view of Kunz, Therapeutic inhibitor of vascular smooth muscle cells, U.S. Patent 5,981,568 (Nov. 9. 1999), under the assertion that Stevens discloses the step of positioning a catheter into a desired location, and that it would have been obvious to provide instructions just as Kunz provided instructions.

This rejection ignores limitations of the claims. The claims require instructions to position the "means for introducing" in the perivascular space to treat a lesion in an intravascular space, and this combination of limitations is not addressed by the rejection. Claim 41 also requires delivering a dose of the therapeutic agent into the perivascular space near the diseased region in the blood vessel. Neither reference used in support the rejection includes this limitation, so the proposed combination does not meet the limitations of the claims, and no prima facie case of obviousness has been made out.

Conclusion

This response has addressed all of the Examiner's grounds for rejection. The rejections based on prior art have been traversed. Reconsideration of the rejections and allowance of the claims is requested.

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